

<b>Office Action Summary</b>	<b>Application No.</b> 10/709,246	<b>Applicant(s)</b> BOOMER ET AL.	
	<b>Examiner</b> ELANA B. FISHER	<b>Art Unit</b> 3733	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3**

10709246 - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.

- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 March 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,4-10 and 13-25 is/are pending in the application.
- 4a) Of the above claim(s) 7-10,20 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,6,13-19 and 22-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. <u>20100525</u> .                           |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application  |
| Paper No(s)/Mail Date _____.  | 6) <input type="checkbox"/> Other: _____.                          |



**DETAILED ACTION**

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1 and 23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment to claims 1 and 23 stating "the inferior and superior surfaces are configured to taper away from one another toward the first end along an entire length thereof from the recess to the first end when the locking mechanism is disposed *and fully distally inserted* in the bore..." (emphasis added) is not supported by the original disclosure. In the submitted amendment, applicant provides paragraphs [0047]-[0050] and figures 1B, 1C, and 1E in the disclosure as support. However, in neither of these, nor throughout the remainder of the disclosure, is anything provided to even suggest that when the locking mechanism is fully within the bore of the clamp member, the inferior and superior surfaces taper away from one another. In the portions of the disclosure pointed to by applicant, the surfaces are either parallel or touching one another.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 4-6, 13-15, and 22-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Morrison (U.S. Patent 6,872,209).

Morrison et al. disclose an implantable spinal connector for mating a spinal fixation element to a spinal anchoring device, comprising: a clamp member (103) having top and bottom portions (109, 108) with a recess (107) formed there between, the top and bottom portions including first and second ends (see diagram provided), the second ends being connected to one another such that the top and bottom portions are a singular piece and are movable between an open position (FIG 42) in which the top and bottom portions are spaced a distance apart from one another, and a closed position (FIG 34) in which the clamp member is adapted to engage a spinal fixation element (B) disposed within the recess (107). The top and bottom portions including inferior (103.1) and superior (103.2) surfaces, respectively, which extend from the recess (107) to the first end (FIG 42). The clamp member further including a bore (117, 118) located between the recess and the first end and extending through the top and bottom portions for receiving a locking mechanism (80) for locking the top and bottom portions in the closed position (FIG 34). The bore (117, 118) includes a threaded (115c) portion in at least one of the top and bottom (118) portions for mating with corresponding threads formed on at least a portion of the locking mechanism (FIG 36). Furthermore, the inferior and superior surfaces (103.1, 103.2) are configured to taper away from one another toward the first end along

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an entire length thereof from the recess (107) to the first end when the locking mechanism is disposed and fully distally inserted in the bore extending through the top and bottom portions (FIG 34; FIG 36). Additionally, the top and bottom portions are biased to the open position (FIG 42) such that a force greater than the biasing force must be applied to move the top and bottom portions to the closed position.

Moreover, the recess (107) has a concave shape and is formed in each of the inferior surface of the top portion and the superior surface of the bottom portion of the clamp member (FIG 42). Additionally, there is a locking mechanism (80) disposable through the bore (117, 118) and effective to lock the top and bottom portions in the closed position to retain a spinal fixation element there between (FIG 34), wherein the locking mechanism (80) comprises a fastening element having a head (82) and a shaft (84), and wherein one of the bore formed in the top portion and the bore formed in the bottom portion of the clamp member is adapted to freely rotatably receive the threaded shaft of the fastening element, and the other one of the bore formed in the top portion and the bore formed in the bottom portion is internally threaded to mate to threads formed on at least a portion of the shaft of the fastening element (FIG 36). Further, the fastening element includes a flange (86) formed there around and adapted to at least temporarily mate the fastening element to a spinal anchoring device. Morrison further teaches that the clamp member (103) is formed from a material that allows the clamp member to deform around a spinal fixation element disposed between the top and bottom portions when the clamp member is locked in the closed position (Column 8, lines 1-4).

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 16-19 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morrison (U.S. Patent 6,872,209).

Morrison discloses a connector according to claim 14 and 24 above, and additionally discloses that the fastening element (80) including a mating element in the form of a socket formed on a distal-most end thereof for mating with a driver tool (FIG 36). However, Morrison fails to disclose that the threads in the bore (115c) are located in the top portion (117) of the bore. It would have been obvious to one skilled in the art to modify the clamp taught by Morrison to have the threads extend to the top portion of the bore, since it would provide controlled entry of the fastening element into the bore at an earlier time than that currently provided.

Additionally, Morrison fails to disclose that the threads in the bore and on the shaft are left-handed threads. It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to have left-handed threads, since it is a configuration a person of ordinary skill in the art would find obvious for the purpose of providing threads. *In re Dailey and Eilers*, 149 USPQ 47 (1966).

***Response to Arguments***

7. Applicant's arguments filed March 29, 2010 have been fully considered but they are not persuasive.

With regards to applicant's arguments, examiner respectfully disagrees. First, applicant argues that the new matter rejection was improper, since FIG 1C of applicant's originally filed drawings shows a taper between the inferior and superior surfaces when the locking mechanism is fully distally inserted. Examiner maintains that FIG 1C and the specification do not clearly show the claimed taper. However, even if examiner concedes that the taper is shown, FIG 1C does not provide sufficient support for the elected invention disclosed in FIG 1E (see applicant's response submitted April 26, 2007). On May 25, 2010 examiner and applicant's representative had a telephone interview, initiated by examiner, during which applicant's representative stated that the features of FIG 1C are present in FIG 1E. However, paragraph 53 of applicant's specification merely states, "Referring to FIG 1E, a clamp member 50 is shown that is similar to clamp member 10 shown in FIGS 1A-1D..." This language represents the only comparison of the clamp in FIG 1E to the clamp in FIG 1C. It does not provide any indication of what those similarities are. Neither the originally filed drawings, nor the originally filed claims, nor the originally filed specification disclose or allow one to infer that the clamp in FIG 1E has a taper between the superior and inferior surfaces when the locking mechanism is "fully distally inserted." Therefore, examiner maintains the new matter rejection under 35 U.S.C. 112, 1st paragraph.

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Next, applicant argues that the Morrison reference fails to teach the claimed invention, since FIG 34-36 fail to disclose that the locking mechanism (80) is fully distally inserted within the bore. Applicant takes the position that the locking mechanism is not fully distally inserted within the bore because of the language presented at the top of column 8 setting forth "subsequent tightening..." (i.e. the locking mechanism can be further tightened than what is presented in the figures). However, examiner would like to draw applicant's attention to the bottom of column 7 which sets forth that "Clevis 103 wraps around the shafts of vertebral anchor B when threads 82 of screw 80 are threadably received by internally threaded bore 115c of bolt 102 (as best show in FIG 36)." Morrison goes on to disclose that, "Tightening of the screw (80) results in curved shoulder (86) bearing against pocket (90)." This initial tightening of the screw results in a full distal insertion of the locking mechanism, since in results in the head of the locking mechanism bearing against the bore. It is not until further tightening occurs that the surfaces move towards one another. While applicant argues that this subsequent tightening means the surfaces do not taper from one another, the claim does not require that full distal insertion occurs when the clamp is fully in its operative state. Additionally, Morrison merely states that the surfaces towards each other during this subsequent tightening. The reference does not teach that the surfaces of the clamp are not tapering from one another. Accordingly, examiner maintains the rejection.

### ***Conclusion***

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).



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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELANA B. FISHER whose telephone number is (571)270-3643. The examiner can normally be reached on Monday through Friday from 8:30AM to 5:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571)272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Elana B Fisher/

Examiner, Art Unit 3733`

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733